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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC. *Plaintiff/Counter-Defendant,* v. INTUITIVE SURGICAL, INC., *Defendant/Counterclaimant.*	Case No. 3:21-cv-03496-VC Honorable Vince Chhabria **PLAINTIFF SURGICAL INSTRUMENT SERVICE COMPANY, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND BRIEF IN SUPPORT** Hearing: June 8, 2023 Time: 10 AM PT Courtroom: Courtroom 5, 17th Floor Judge: The Honorable Vince Chhabria Complaint Filed: May 10, 2021

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR RESPECTIVE COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, at 10:00 a.m., or as soon thereafter as the matter may be heard, in the courtroom of the Honorable Vince Chhabria, United States District Judge for the Northern District of California, located at 450 Golden Gate Avenue, San Francisco, CA 94102, Plaintiff Surgical Instrument Service Company, Inc. will move the Court to grant partial summary judgment in its favor as on Defendant Intuitive Surgical, Inc.'s Affirmative Defense and Counts 1-4 of its Counterclaims.

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I. INTRODUCTION

Plaintiff, SURGICAL INSTRUMENT SERVICE COMPANY ("SIS"), respectfully submits that the Court should enter partial summary judgment against Defendant, INTUITIVE SURGICAL, INC. ("Intuitive") as to all of Intuitive's FDA-related counterclaims and defenses. All of those claims and defenses are predicated on Intuitive's bare allegation – unsupported by FDA guidance or an official, final determination -- that SIS and its technology partners are "remanufacturers" and thus, are required to obtain FDA regulatory clearance for their EndoWrist servicing business. SIS and its technology partners' EndoWrist surgical instrument servicing includes, *inter alia*, extending the intended use life of this multi-use device. That extension is includes resetting Intuitive's built-in-self-destruct usage counter, thus allowing customers to avoid having to throw away EndoWrist instruments after only 10 uses.

Intuitive's FDA-related claims and defenses are subject to dismissal as a matter of law because the FDA has not issued final guidance on when or what servicing activities constitute "remanufacturing" of a medical device. Historically, FDA has never asserted its authority in an attempt to regulate companies that repair or service multi-use medical devices such as EndoWrists. Indeed, FDA acknowledges the long-standing and continuing lack of clarity in the distinction between "servicing" and "remanufacturing" for purposes of regulating medical devices. Additionally, Congress has considered but not yet passed legislation necessary to give FDA express statutory authority to regulate medical device servicing.

Relevant to the issues in the present action, FDA has declined to render an official, final determination as to whether service activity extending the intended use life of multi-use medical devices and instruments requires 510(k) clearance. Until Congress enacts legislation or the FDA issues binding guidance, service providers such as SIS and its technology partners are under no legal obligation to obtain FDA regulatory clearance through a 510(k) pre-market notification submission to conduct their business. Consequently, in order to proceed and resolve Intuitive's FDA-related defenses and counterclaims, the Court would be required to create regulatory policy on a question of first impression and make a determination that the

FDA has not made. Put another way, in order to find that SIS has made any false or misleading statements related to whether 510(k) clearance is required for its activites, or that not obtaining 510(k) clearance raises a defense of unclean hands, the Court would be required to *create* FDA guidance and preemptively make decisions based on that newly created guidance, where FDA has explicitly declined to do so.

II. FACTS

A. Intuitive's Business Model And Self-Destruct Use Counter

Intuitive da Vinci "systems consist of a surgeon console or consoles, a patient-side cart, and a high-performance vision system and use proprietary instruments and accessories." JVH Decl., Ex. 1 at 90. "The patient-side cart holds electromechanical arms that manipulate the instruments inside the patient." *Id.* at 7. "The da Vinci Surgical System generally sells for between $0.5 million and $2.5 million, depending upon the model, configuration, and geography, and represents a significant capital equipment investment for [Intuitive] customers when purchased." *Id.* at 61. Intuitive's "[r]ecurring revenue consists of instruments and accessories revenue, service revenue, and operating lease revenue." *Id.* at 62. "Instruments and accessories revenue has grown at a faster rate than systems revenue over time[,] increas[ing] to $3.52 billion in 2022." *Id.* "Most of the various instruments that [Intuitive] manufacture[s] incorporate EndoWrist technology with wristed joints for natural dexterity and tips customized for various surgical procedures." *Id.* at 8.

Intuitive developed the core design for its EndoWrist instruments in the 1990's. JVH Decl., Ex. 2 at 1 (listing a 1997 filing date for a core EndoWrist patent); JVH Decl., Ex. 3 at 30:9-31:12 (acknowledging that Intuitive's Ken Salisbury –"who inventented the EndoWrist" – did so "[i]n the 1990s"). For almost all EndoWrists – from their original 1990s design to the present day[1] – a robot arm with four rotating motors interfaces with and turns four corresponding "discs" of an attached EndoWrist, allowing surgeons to remotely control the motion of the "distal" (or working) end of the instrument about multiple degrees of freedom

[1] Almost all patents on EndoWrist instruments have long since expired. *See* JVH Decl. Ex. 4 at 2 (listing, in Intuitive's online "Patent Notice," only two patents for S, Si, and Xi EndoWrists that were filed after 2002).

known as of yaw, pitch, roll, and grip. JVH Decl., Ex. 5 at 21:10-25, 40:2-41:10, 49:21-52:20 (Intuitive's Director of Instrument Design Engineering, discussing operational principles and similarities between Si and Xi EndoWrists). This provides multiple advantages over traditional "minimally invasive" surgeries, such as movements that are unavailable with surgeon-held laparoscopic instruments and improved ergonomics over laparoscopic procedures. The general operating principles of the EndoWrist instruments have not changed significantly from the launch of S EndoWrists in 2005 through the present day, and utilize similar discs, pulleys, cables, and rods that receive and translate motion from the motors of the robot arm to control the distal end of the EndoWrist. JVH Decl., Ex. 5 at 17:10-20:19, 49:21-52:20. There are not – and there have never been – electronics of the EndoWrist that "have any electrical or physical connection" to the EndoWrist mechanical components. JVH Decl., Ex. 7 at 108:18-109:22

While some initial EndoWrists may be supplied with a da Vinci system, most instruments are purchased separately over the da Vinci system's multi-year useful life. JVH Decl., Ex. 8 at 90:15-91:10. The install base of da Vinci systems has steadily grown, such that almost all U.S. hospitals, including most smaller and rural hospitals, find it necessary to have at least one da Vinci system. JVH Decl., Ex. 6 at ¶ 37; JVH Decl., Ex. 9 at ¶ 24. Over 99% of robotic surgical systems used in minimally invasive surgery in the U.S. are Intuitive da Vinci Systems. *Id.* at at ¶¶ 83-85. Once a da Vinci system is purchased, there are no alternative suppliers of new EndoWrist instruments. *Id.* at ¶ 113.

Intuitive controls the frequency of EndoWrist instrument replacement via a built-in self-destruct mechanism it calls a "use counter." JVH Decl., Ex. 10 at ¶¶ 93. A simple memory chip within the EndoWrist instruments decrements every time the EndoWrist instrument is used in surgery, without regard to the actual time or rigor of usage of the EndoWrist in the surgery. *Id.* at ¶¶ 103-107. When the use count (until recently, 10 uses in most instruments) reaches zero, the da Vinci system will no longer recognize the EndoWrist instrument, which must then be thrown away. *Id.* at ¶ 105. Intuitive's use count values were set by its marketing department, and while Intuitive claims to have performed testing to validate those use limits,

for the vast majority of EndoWrist instruments, Intuitive stopped testing once it satisfied its marketing-determined use limits, despite none of the tested instruments experiencing any failures. *Id.* at ¶¶ 118-120; JVH Decl., Ex. 11 at 53:4-57:15, 61:3-66:9; JVH Decl., Ex. 12 at 51, 55, 56, 60.

As Intuitive's surgeon expert admits, use limits are virtually non-existent for other multi-use surgical instruments, and Intuitive is the only company he is aware of to impose a self-destruct mechanism on an multi-use instrument. JVH Decl., Ex. 13 at 40:11-42:11. Where the use counter's self-destruct methodology has been extremely successful is in driving the vast majority of Intuitive's profits. Not only is the mechanical operation of EndoWrist instruments largely unchanged from the initial 1990s design, but the cost of producing EndoWrist instruments is in the low hundreds of dollars. JVH Decl., Ex. 14 at 52:6-53:9; JVH Decl., Ex. 15 at 15-17. Nonetheless, Intuitive sells (mostly replacement) EndoWrists for thousands of dollars each, and they now account for the majority of Intuitive's billions of annual revenue and profits. JVH Decl., Ex. 16 at 11; JVH Decl., Ex. 1 at 62.

B. SIS Sells EndoWrist Repair Services To Major Hospitals Systems And Group Purchasing Organizations, Potentially Saving Hospitals And Patients Hundreds Of Millions Annually

By early 2019, medical technology companies such as Rebotix Repair and Restore Robotix had made signficant sales of repaired S/Si EndoWrists to a number of hospitals and systems in the United States. JVH Decl., Ex. 8 at 74:19-76:17. This was based on a high-quality and technologically viable solution including circumventing the S/Si self-destruct and performing a comprehensive inspection and repair process to ensure that the repaired instrument would operate in the same manner as an Intuitive-provided device. JVH Decl., Ex. 10 at ¶¶ 68-91.

Enter Surgical Instrument Service Company, Inc. ("SIS"). For over 50 years, SIS has worked closely with hospitals to provide efficient, cost-effective, and (most importantly) safe servicing of surgical instruments ranging from stainless instruments to more complex systems

such as surgical video systems and flexible endoscopes.[2] JVH Decl., Ex. 17 at 2; JVH Decl., Ex. 18 at 11:20-12:1. Although still a family-owned business, SIS has achieved a size and scale that allow it to compete with publicly-held goliaths such as Agiliti and Steris. JVH Decl., Ex. 18 at 9:2-11:14, 13:2-18; JVH Decl., Ex. 19 at 9:9-14. Indeed, SIS is one of "three vendors on Vizient national contract in the instrument repair space." JVH Decl., Ex. 20 at 87:7-24. Vizient, in turn, is the country's largest group purchasing organization (GPO) representing thousands of hospitals and health care facilities. JVH Decl., Ex. 19 at 52:25-53:8; JVH Decl., Ex. 20 at 87:2-6.

SIS became aware of the Rebotix EndoWrist repair procedure in spring of 2019, and over the ensuing months, worked with Rebotix to understand the process and potentially bring it to SIS customers, including multiple visits to SIS and Rebotix facilities. JVH Decl., Ex. 18 at 23:18-27:20; JVH Decl., Ex. 20 at 23:9-24:16, 32:21-33:18. SIS developed marketing materials with Rebotix that discuss SIS's position – from 50 years of experience repairing hospitals' instruments without FDA interference – that FDA approval is not required for repair of hospital-owned EndoWrist instruments: "The da Vinci® EndoWrist® is a "multi-use" medical device. Multi-use devices, such as endoscopic instruments, have always been eligible for repair." JVH Decl., Ex. 21 at 6 (SIS095124). As explained by SIS at the time, "The FDA does not regulate, nor certify, repairs. The FDA regulates third party reprocessing companies and single-use devices only." *Id.* at 2 (SIS095120).

SIS began offering the S/Si EndoWrist and repair process to its customer base in fall of 2019, and quickly gained a foothold with major hospital systems in this district as well as numerous other major systems in other regions of the country. JVH Decl., Ex. 20 at 109:9-18, 110:13-24, 116:1-9; JVH Decl., Ex. 8 at 88:7-19. SIS signed an agreement with Vizient specific to EndoWrist repairs, making SIS the only Vizient-approved supplier of EndoWrist

[2] EndoWrists fall somewhere in the middle relative to complexity of devices that SIS typically repairs. For example, the tools on the distal ends of EndoWrists are virtually identical to the tools of conventional forceps, scalpels, scissors and the like. The cable and pulley systems of EndoWrists share many similarities with flexible endoscopes, but are much shorter and do not have to snake through multiple turns. JVH Decl. Ex. 10 at ¶¶ 133-136; JVH Decl. Ex. 22 at 174:19-175:3.

repairs for Vizient's thousands of healthcare member facilities.[3] JVH Decl., Ex. 18 at 77:14-78:20; JVH Decl., Ex. 19 at 52:5-24; JVH Decl. Based on the substantial cost-savings and hospitals' frustration with Intuitive's business practices, hospital demand for the EndoWrist repair service was "monumental." JVH Decl., Ex. 20 44:7-45:22; JVH Decl., Ex. 19 at 50:10-51:24. Every hospital system that discussed the EndoWrist repair service was interested, including "Legacy Health system in Portland, Oregon; Providence health system in the West Coast; Sutter Health; Kaiser Permanente; memorial care; the UC system in California; Banner Health System; Honor Health; Baylor Scott & White in Texas; the university health systems across the country, from Michigan to Duke to North Carolina; Mayo Clinic; Cleveland Clinic; Advocate Aurora; Lahey Health System; Boston Children's Medical Center . . . Piedmont health system, Grady in Atlanta, Johns Hopkins . . . And then, in addition to that, all the Vizient conversations we've had, I've presented to all four regions of Vizient, which basically covers well over 2,000 hospitals in the United States." JVH Decl., Ex. 20 45:2-45:22.

There is there no dispute that SIS's activities have never been challenged by FDA in over 50 years in business: "The FDA stayed out of repair.. . . [I]t has not been a necessity to deal with any regulatory issues with re- -- regarding the repair of surgical instrumentation." JVH Decl., Ex. 23 at 44:18-45:3; JVH Decl., Ex. 20 at 46:3-12.

C. Intuitive Shuts Down The EndoWrist Repair Business With Threats To Shut Down Hospitals' Surgical Robot Programs

Concerned with the escalating adoption of EndoWrist repair in late 2019, Intuitive sent threat letters to virtually every hospital where it discovered use of repaired EndoWrists, including to SIS's customers. *E.g.*, JVH Decl., Ex. 8 at 79:18-81:15, 88:7-19, 92:17-94:7; JVH Decl., Ex. 24; JVH Decl., Ex. 25. The threats in those letters were explicit – if the hospital continued to use repaired S/Si EndoWrists, Intuitive would effectively shut down the hospital's entire robotic surgery program, including by withholding service for the surgical

[3] SIS also presented to the Vizient sales force at Vizient regional meetings, ensuring that word of the EndoWrist repair service would also be shared by Vizient personnel. JVH Decl. Ex. 20 at 44:19-45:22, 88:8:14.

robots and voiding the warranty for the da Vinci systems (not just the EndoWrists). JVH Decl., Ex. 24 at 2-3; JVH Decl., Ex. 25 at 2-3. For example:

> Intuitive may no longer accept your service calls for such Systems. Should Intuitive or its personnel determine, after having accepted a service call or a purchase order for a service call, such as after an Intuitive Field Service Engineer arrives at your site for a service call, that the System has been used with instruments refurbished or modified by an unauthorized third party, Intuitive may not provide service for such a System.

E.g., JVH Decl., Ex. 24 at 3; JVH Decl., Ex. 25 at 3. Faced with the shutdown of their robotic surgery programs, all SIS customers (and to SIS's knowledge, all EndoWrist repair customers) stopped using repaired EndoWrists. JVH Decl., Ex. 18 at 39:21-40:5, 41:23-44:19; JVH Decl., Ex. 19 at 55:12-56:7, JVH Decl., Ex. 22 at 39:3-41:4.

D. Intuitive Attempts To Enlist FDA And Makes False Statements To Hospitals

Intuitive's threat letter to hospitals also contends that "any modification to allow for use of a da Vinci product beyond its labeled useful life exceeds the scope of the original clearance by expanding the FDA cleared indications for use." *E.g.*, JVH Decl., Ex. 25 at 3. According to Intuitive's hospital threat letter, services such as those provided by SIS require an additional FDA clearance: "Engaging in such activities without first obtaining a new clearance to do so misbrands the product under 21 U.S.C. § 351." *Id.*

Intuitive also brought this campaign directly to FDA in January of 2020, alleging that "companies are modifying lntuitive's robotic instruments in order to extend their use beyond the number of uses for which they have been validated . . . ." JVH Decl., Ex. 26 at 1. According to Intuitive, "the companies performing these activities **are clearly 'Remanufacturers,'** as that term is defined in FDA's regulations." *Id.* at 2 (emphasis added). According to Intuitive, "[a]s remanufacturers, these companies are subject to the full range of device manufacturer requirements, including, among other things, obtaining clearance of a 510(k) submission, and complying with Quality System Regulation, MDR Reporting, Reports of Corrections and Removals, and Establishment Registration and Device Listing requirements." *Id.* at 3

As discusssed in § III below, Intuitive made these representations to hospitals and to FDA at a time when FDA had explicitly and publicly stated that it was undecided as to what activities constitute remanufacturing and are thus potentially subject to FDA regulation such as 510(k) approval.

E. Intuitive's FDA-Related Claims And Defenses Are Based On SIS And Its Technology Partner Purportedly Being "Remanufacturers" That Are Required To Obtain 510(k) Clearance

Intuitive's only Affirmative Defense alleges in part that "SIS's claims are barred, in whole or in part, by the doctrine of unclean hands because SIS has acted contrary to applicable FDA regulations . . . ." Dkt. 75 at p. 39 ("First Defense"). Intuitive's unfair competition and false advertising claim under the Lanham Act (Count 1) and its derivative state law claims (Counts 2-4) similarly rely in part on allegations that "SIS has made numerous false and misleading statements, including . . . that the 'repair' and/or resulting instruments do not require clearance by the FDA[.]" *Id.* at ¶ 85 (Count 1), ¶¶ 93, 99, 102 (referring to "conduct detailed above" in Count 2, "statements detailed above" in Count 3, and "above-detailed deceptive and fraudulent conduct" in Count 4).

To support its allegation that "SIS has acted contrary to FDA regulations[,]" Intuitive relies on a purported requirement that SIS obtain 510(k) clearance: "SIS further sold a service to customers that required 510(k) clearance under FDA rules and regulations, despite not having such clearance." Dkt. 75, Counterclaim ("CC") at ¶ 77. According to Intuitive, "FDA cleared EndoWrists as limited use or 'resposable' instruments with use limits, and any modification of EndoWrists by a third party to increase the use limits requires a new 510(k) clearance." *Id.* at ¶ 4. Intuitive alleges SIS's initial supplier "Rebotix never received 510(k) clearance from the FDA for its operations or for the marketing and sale of EndoWrists with overridden use counters [and] [u]pon information and belief, SIS knew that Rebotix never received 510(k) clearance and was aware of Rebotix's prior communications with the FDA in which Rebotix failed to obtain any such clearance." *Id.* at ¶ 50.

Intuitive further alleges that "[b]ased on the false premise that the [SIS] service is merely a 'repair' of EndoWrists, SIS … misinforms customers that 'repaired' instruments do not

require 510(k) premarket clearance by the FDA." Dkt. 75, CC at ¶ 11. SIS instead purportedly engages in "unauthorized modification and remanufacturing of Intuitive's EndoWrist surgical instruments ('EndoWrists')" in a manner that is not "consistent with both EndoWrists' design specifications and FDA clearances." Dkt. 75, CC at ¶ 1. Intuitive thus alleges that SIS performs "remanufacturing," not "repair." *E.g.,* Dkt. 75, CC at ¶¶ 8, 61, 64, 86, 92, 94, 97.

III. STATUTORY AND REGULATORY BACKGROUND

A. Statutes Providing For FDA Regulation Of Medical Device And Instrument Manufacturers

The predecessor agency to the Food and Drug Administration ("FDA") originated with the 1906 Pure Food and Drugs Act. 34 Stat. 768, Ch. 3915 (JVH Decl., Ex. 27 at 768). The 1938 Federal Food, Drug and Cosmetic Act ("FD&C Act") stated that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application [filed with the Secretary] is effective with respect to such drug." 52 Stat. 1040 at § 505(a) (JVH Decl., Ex. 28 at 1052). As FDA explained in a 2006 article entitled "Medical Device and Radiological Health Regulations Come of Age,"[4] from 1938 until the 1976 passage of the "Medical Device Amendments" to the FD&C Act, "devices were subject only to policing by the FDA" and "[t]here was . . . no requirement for premarket testing, review, or approval." JVH Decl., Ex. 29 at 3-4.

The Medical Device Amendments set forth requirements for premarket approval of medical devices, including through amendments such as to Section 510 of the FD&C Act and new Sections 513-521. *See* 90 Stat. 539 (JVH Decl., Ex. 30 at 539-540, 579-580). Section 510 regarding "REGISTRATION OF **PRODUCERS** OF DRUGS" was "amended by inserting 'AND DEVICES' after 'DRUGS.'" *Id.* at 579 (emphasis added). Section 510(k) was added to require "[e]ach person *who is required to register* under this section [510] and **who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device**" to comply with certain reporting

[4] Available at https://www.fda.gov/files/about%20fda/published/Medical-Device-and-Radiological-Health-Regulations-Come-of-Age.pdf

requirements, including reporting compliance with the requirements of Section 514 (Performance Standards) and Section 515 (Premarket Approval). *Id.* at 580 (emphasis added); *see also* 21 U.S.C. § 360(k). Registration, in turn, is limited to "every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices[.]" 21 U.S.C. § 360(b)(2) ("Section 510(b)(2)"); *see also* 90 Stat. 579 (inserting "device or devices"). The "Definitions" of Section 510 is clear that, as with the reporting requirements of § 510(k), Section 510's registration requirements are limited to entities in the original production and distribution chain of the medical device:

> [T]he term "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package **in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user**[.]

21 U.S.C. § 360(a)(1) ("Section 510(a)(1)") (emphasis added); *see also* 90 Stat. 579 (inserting "device package," "device," and "user").

B. Statutes Providing For Post-Distribution FDA Regulation Of Medical Devices And Instruments

In two instances, Congress has expanded FDA's authority over medical devices to cover post-distribution activities, including by requiring reporting of medical device failures by hospitals and by authorizing regulation of reprocessors of single-use devices. Section 519 of the original Medical Device Amendments included recordkeeping and reporting requirements that applied to "[e]very person who is a manufacturer, importer, or distributor of a device intended for human use[.]" 90 Stat. (JVH Decl., Ex. 30) at 564. 1990's Safe Medical Devices Act ("SMDA") expanded Section 519's reporting requirements to "[w]henever a device user facility receives or otherwise becomes aware of information that reasonably suggests that there is a probability that a device has caused or contributed to the death of a patient of the facility" or "caused or contributed to the serious illness of, or serious injury to, a patient of the facility." 104 Stat. (JVH Decl., Ex. 31) 4511.

The 2002 Medical Device User Fee and Modernization Act ("MDUFMA") "expand[ed] FDA regulation of the medical device reprocessing industry" (Congressional Record 107 (2002) – JVH Decl., Ex. 32 at S10754 (C. Dodd)) by "regulating the reprocessing of single use devices" *Id* at S10755 (H. Reid). The MDUFMA accomplished this by imposing, under the heading of "SINGLE-USE MEDICAL DEVICES," certain "LABELING" and "PREMARKET NOTIFICATION" obligations on entities involved with "reprocessed single-use devices." *See* 116 Stat. (JVH Decl., Ex. 33) at 1616-20. Specific to 510(k) approvals, the MDUFMA required that "The Secretary shall identify such [reprocessed single-use] devices or types of [reprocessed single-use] devices for which reports under such subsection [510(k)] must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification." *Id.* at 1616-17. The definition of "reprocessed" within these sections is limited to the context of single-use devices and a "single-use device" is limited to "a device that is intended for one use, or on a single patient during a single procedure." *Id.* at 1619-20.

C. OEMs Have Tried And Failed To Pass Statutes To Require 510(k) Clearance For Servicing Of Multi-Use Devices And Instruments Such As EndoWrists

On April 25, 2017 – following 40 years of failed lobbying efforts by medical device OEMs to get FDA to require registration, approval, or other regulation of third-party servicers of medical devices such as SIS – H.R. 2118 was introduced in the House of Representatives. 115 H.R. 2118 (JVH Decl., Ex. 34). The proposed bill would have amended Section 510 of the FD&C Act to define "servicing" as "include[ing], with respect to a device, refurbishing, reconditioning, rebuilding, remarketing, repairing, or other servicing of the device by a person other than the manufacturer of the device." *Id.* at § (r)(2). The bill also proposed amending Section 510's registration requirements to include "any person who owns or operates any establishment in any State engaged in the servicing of a device or devices, or is otherwise

engaged in the servicing of a device or devices" and to make servicers subject to Section 519's reporting requirements, "by striking 'manufacturer or importer' each place it appears and inserting 'manufacturer, servicer, or importer[.]'" *Id.* at § 2-(b)(1)(A) and § 2-(r)(1).

The bill that became the 2017 Food and Drug Administration Reauthorization Act ("2017 Act"), as introduced on May 16, 2017, did not include any discussion of device servicing. *See* H.R. 2430 (JVH Decl., Ex. 35). The final bill passed later that year rejected the OEMs' attempt impose new 510(k) clearance on servicing. Instead, the 2017 Act required, in Section 710, that FDA prepare a "REPORT ON SERVICING OF DEVICES." Public Law 115-52; 131 Stat. 1006 (JVH Decl., Ex. 36) at 1067-68. Section 710 of the 2017 Act required FDA to "post on the internet website of the Food and Drug Administration a report on the continued quality, safety, and effectiveness of devices (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(h))) with respect to servicing (as defined in subsection (c))." *Id.* at 1067-68. Subsection (c) of Section 710 of the 2017 Act defined "servicing" to include "remanufacturing": "SERVICING DEFINED.—In this section, the term 'servicing' includes, with respect to a device, refurbishing, reconditioning, rebuilding, remarketing, repairing, **remanufacturing**, or other servicing of the device." *Id.* at 1068.

Sections 710(a)(1)-(2) of the 2017 Act required FDA's report to include findings resulting from a 2106 proposed FDA rule and from a 2016 public workshop on the proposed rule. *Id.* at 1068. Section 710(a)(3)-(4) required FDA's report to include "a description of the statutory and regulatory authority" over servicing (including remanufacturing) and "whether additional authority is recommended[.]" *Id.* The 2016 proposed rule, workshops and FDA's resulting "FDARA 710 – 3rd Party Servicing Report" report are discussed further in § III(D), *infra*.

Unhappy with the results of the 2017 Act, the FDARA 710 report, and FDA's continued failure to require 510(k) clearance for servicing, the OEMs took a different tack in the last year. On March 28, 2022, H.R. 7253 was introduced in Congress "[t]o amend the Federal Food, Drug, and Cosmetic Act to provide for clarification of requirements for the remanufacturing of medical devices, and for other purposes." 117 H.R. 7253 (JVH Decl., Ex. 37) at 1. Titled the "Clarifying Remanufacturing to Protect Patient Safety Act of 2022," H.R.

7253 proposed to change the definition of "manufacturing" in Section 510 of the FD&C Act to add remanufacturing – thus changing who must register and potentially obtain Section 510(k) clearance – as follows (**new language in bold**):

> Section 510 of the Federal Food, Drug, and Cosmetic 9 Act (21 U.S.C. 360) is amended—
>
> (1) by subsection (a), by amending paragraph (1) to read as follows:
>
> "(1) The term 'manufacture, preparation, propagation, compounding, or processing' shall include **the following:**
>
> "**(A)** Repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.
>
> **(B) Remanufacturing of any finished device by engaging in any act that could significantly change the performance or safety specifications, or intended use, of the finished device, including by significantly changing—**
>
> **(i) a sterilization method;**
>
> **(ii) a reprocessing instruction;**
>
> **(iii) a control mechanism, operating principle, or energy input or output;**
>
> **(iv) the anatomical location of use; or**
>
> **(v) the design[.]**

Id. at 2 (emphasis added).[5] As of the date of this filing, the OEMs have not been successful in persuading Congress to change the definition of "manufacture" under Section 510 of the FD&C Act to include "remanufacturing" or to enumerate specific activities that require 510(k) clearance. *See* JVH Decl., Ex. 38.

D. FDA Has Not Issued Final Guidance On What Servicing Activities Constitute Remanufacturing That Requires 510(k) Clearance

FDA first proposed a definition for "remanufacturing" in 1996: "Remanufacturer means any person who processes, conditions, renovates, repackages, restores, or does any other act

[5] The bill also sought to impose new requirements for "Device Remanufacturing Public Education" and a program for "Enhanced Communications Regarding Remanufacturing" that allows any third party to "express[] concerns that an entity that is remanufacturing devices – (A) is not registered under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360)[.]" 117 H.R. 7253 at §§ (3)-(5) (JVH Decl. Ex. 37 at 3-7).

to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." 61 Fed. Reg. 52610 (JVH Decl., Ex. 39) at 52641, 52656. As FDA explained in a 1997 Federal Register Notice, "[r]emarketing used devices may consist of activities that significantly change the finished device's performance or safety specifications, or intended use . . . [and thus] constitute 'remanufacturing' as defined in the Quality System regulation (QS)[.]" 62 Fed. Reg. 67011 (JVH Decl., Ex. 40).

FDA largely left these issues alone for nearly 20 years,[6] seeking to revisit them in 2016 after certain "[s]takeholders have expressed concerns" regarding "some third-party entities who refurbish, recondition, rebuild, remarket, remanufacture, service, and repair medical devices . . . ." 81 Fed. Reg. 11477 (JVH Decl., Ex. 41) at 11478. FDA requested comments and indicated its intent to hold public meetings regarding proposed definitions and appropriate regulatory schemes for the following: "Recondition," "Service," "Repair," "Refurbish," "Remanufacture," and "Remarket." *Id.* at 11478-79.

FDA followed up with notice of a public workshop entitled "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers", which was scheduled for October 2016. 81 Fed. Reg. 46694 (JVH Decl., Ex. 42). In the summary discussing the upcoming workshop, FDA stated that one topic would be **"whether these activities should appropriately be regulated by FDA or a non-governmental organization.**" *Id.* (emphasis added). As the Deputy Director for Regulatory Oversight and Analysis in the Division of Analysis and Program Operations of FDA's Office of Compliance explained at one of those public meetings (held October 27, 2016):

> Then the quality system regulation came along. And there was a decision in '93 to update what was then the CGMPs and we wanted to codify basically

[6] "Over the past 20 years, the Center for Devices and Radiological Health has sought to clarify our regulatory requirements and expectations, under part 820 (21 CFR part 820), to entities servicing, refurbishing, rebuilding, reconditioning, remarketing, and remanufacturing medical devices." 81 Fed. Reg. (JVH Decl. Ex. 41) at 11478. However, other than some specific discussions of x-ray and laser systems, the only clarification that FDA mentioned over those 20 years was that "[i]n the Federal Register on December 4, 1998 (63 FR 67076), refurbishers and servicers of medical devices were excluded from the requirement to comply with the 1997 Quality System Regulation under part 820." *Id.*

> what the policy was. And so the proposed rule included third-party servicers and refurbishers as being subject to all of the proposed changes in the new quality system regulation.
>
> Well, there were a lot of comments about this; there was a lot of contentious discussions about it. And it got to the point where this particular subject could have derailed the proposed rule from becoming final.
>
> * * *
>
> So 1997 we actually published what is known as Advance Notice of Public Rulemaking which is sort of the pre-step of having a proposed rule. And this is where the refurbisher, reconditioner, servicers, all that verbiage comes from. . . . At that time no one could agree what the right term was. **And I think we are still at that point where nobody really knows what the best term to use for this particular situation is**.
>
> * * *
>
> Since 1998 no one has had to register with us, no one has been subject to inspection except for cause if there is a concern that you are not really refurbishing but you are actually remanufacturing a device because you are changing the intended use. **So the industry has not really had any involvement with FDA except our interactions with some of the trade associations since 1998.**
>
> So here we are today. So in March we published the request for comment about this subject. We got 177 comments, more than twice what we got 20 years ago. And we are here today to talk about what those comments said and some of the other issues that were raised.

FDA Public Meeting, October 27, 2016 (JVH Decl., Ex. 43) at 16-21 (emphasis added).

FDA issued its "Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices In accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA)" in May of 2018. [7] JVH Decl., Ex. 44 (the "2018 FDARA Report"). The 2018 FDARA Report acknowledged that "FDA generally has not enforced FD&C Act requirements with respect to servicing activities . . . ."[8] Ex. 44 at 4. FDA

[7] FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Device, (published by the FDA in May 2018, and available at https://www.fda.gov/media/113431/download) (hereafter "FDA 2018 Report").

[8] This statement applied equally to "remanufacturing." *Compare* 2018 FDARA Report (JVH Decl. Ex. 44) at p.iii n.2 ("[G]iven the definition in section 710(c) of FDARA, **unless otherwise specified in this report** (e.g., when expressly describing the differences in FDA regulation concerning servicing and remanufacturing), **references to 'servicing' throughout this report generally include all of the activities identified in section 710(c)**") (emphasis added); *with* 131 Stat 1006 (JVH Decl. Ex. 36) at 1068 (Section 710(c) of FDARA, stating that "**[i]n this section, the term 'servicing' includes**, with respect to a device, refurbishing, reconditioning, rebuilding, remarketing, repairing, **remanufacturing**, or other servicing of the device" (emphasis added)).

ultimately concluded that it would not impose additional or different regulatory requirements on the third-party servicers of medical devices:

> The currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers, of medical devices that would justify imposing additional/different, burdensome regulatory requirements at this time;
>
> Rather, the objective evidence indicates that many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices;
>
> * * *
>
> We believe the currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing of medical devices, including by third party servicers, that would justify imposing additional/different burdensome regulatory requirements at this time.

2018 FDARA Report at p. i. FDA did, however, decide to "Clarify the Difference Between Servicing and Remanufacturing":

> Because of the apparent confusion we have heard from stakeholders concerning the difference between servicing and remanufacturing activities, FDA intends to publish guidance to assist in differentiating these activities to allow more consistent interpretation and categorization. In turn, this will clarify regulatory responsibilities for entities performing these activities and allow FDA to focus its regulatory oversight on those activities that have the greatest impact on the quality, safety, and effectiveness of medical devices. **In accordance with good guidance practices, FDA intends to publish the guidance in draft form and accept public comments <u>before issuing final guidance</u>.**

2018 FDA White Paper at pp. 24-25 (emphasis added).

FDA issued a White Paper "For Discussion Purposes Only" to facilitate a 2018 workshop entitled "Medical Device Servicing and Remanufacturing Activities"[9] JVH Decl., Ex. 45 ("the 2018 FDA White Paper"). FDA indicated that "[t]his white paper is for discussion purposes only and does not represent draft or final guidance." *Id.* at p. 1.

Following up on these workshops and the White Paper, in June 2021, FDA issued a "Draft – Not for Implementation" that "Contains Nonbinding Recommendations" regarding "Remanufacturing of Medical Devices." JVH Decl., Ex. 46 (the "2021 Draft

[9] White Paper: Evaluating Whether Activities are Servicing or Remanufacturing, published by FDA in December 2018 and available at https://www.fda.gov/media/117238/download.

Remanufacturing Guidance"). In the Introduction, FDA acknowledged that the continuing lack of clarity in the distinction between "servicing" and "remanufacturing" impacts FDA's regulatory authority and the regulatory responsibilities of entities performing such activities:

> [T]here is a lack of clarity regarding the distinction between "servicing" and "remanufacturing" of a device. Most notably, remanufacturing has implications for the regulatory responsibilities of entities performing these activities.

Id. at p. 1. FDA stated that "[t]his draft guidance document is being distributed for comment purposes only." *Id.* at Cover Page. Further, "[t]his draft guidance, **when finalized**, will represent the current thinking of the Food and Drug 5 Administration (FDA or Agency) on this topic." *Id.* (emphasis added). The 2021 Draft Remanufacturing Guidance has not been finalized as of the date of this filing. *See, e.g.*, https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/remanufacturing-and-servicing-medical-devices (live FDA website providing links to draft guidance, white papers, and workshops).

E. FDA Has Declined To Decide Whether Extending The Intended Use Life Of Multi-Use Devices And Instruments Requires 510(k) Clearance

Relevant to the present action, in the 2018 FDA White Paper, FDA sought comment as to whether certain example scenarios were "servicing" or "remanufacturing," explaining that "[s]takeholders should comment on whether the accompanying text and flowchart adequately and clearly capture the thought process that would distinguish between servicing and remanufacturing activities." 2018 FDA White Paper (JVH Decl., Ex. 45) at p.12. In one of the scenarios, **"[s]ome components/parts/materials have a defined intended use life which limits the life expectancy of the device . . . [and] [a]ctivities are performed to extend the device's intended use life."** *Id.* at pp. 15-16 (emphasis added).

FDA's 2021 Draft Remanufacturing Guidance laid out 15 dense pages of "Definitions," "Guiding Principles," "Relevant Considerations," and a multi-stage flowchart through which industry participants could ultimately reach alternatives of "Likely Not Remanufacturing" or "Likely Remanufacturing." 2021 Draft Remanufacturing Guidance (JVH Decl., Ex. 46) at pp. 1-15. Perhaps recognizing that these sections of the Draft Guidance provided minimal clarity,

FDA's Draft Guidance also provided "Decisions" as to whether certain of the example scenarios were "Remanufacturing" or "Not Remanufacturing." *Id.* at pp. 18-32. Notably, the example scenario from the 2018 White Paper where "[a]ctivities are performed to extend the device's intended use life" was omitted from the 2021 Draft Remanufacturing Guidance without a "Decision." *Compare id.* at pp. 18-32; *with* JVH Decl., Ex. 45 at pp. 15-16.

Less than one month after Intuitive wrote FDA asking it to investigate the supplier of SIS's initial technology solution and repair process (Rebotix), FDA employees reached out to Rebotix stating that "we believe that a 510(k) is needed to continue your operation." *Compare* JVH Decl., Ex. 26 at 1-2, 6 (on January 29, 2020, writing to FDA stating that Rebotix is "engaging in the unlawful remanufacturing of EndoWrist Instruments" and "request[ing] that FDA promptly investigate the EndoWrist Remanufacturers' activities"); *with* JVH Decl., Ex. 47 at 2 (on February 28, 2020, a "Biomedical Engineer" from FDA following up on February 20 and February 28 phone calls, and stating that "we believe that 510(k) is needed before you continue your operation").

These conversations continued for over a year, but never formally rose above a "Team Lead" who was "not a particularly high level person." JVH Decl., Ex. 48 (correspondence with "Team Lead"); JVH Decl., Ex. 49 at 99:23-100:3. Faced with continued intransigence from low-level FDA employees, Rebotix asked to formally appeal what these FDA employees had referred to as a "decision." JVH Decl., Ex. 48; JVH Decl., Ex. 49 at 98:18-100:3. "[A]fter other people in the FDA, including higher level people got involved, then we received this letter to kind of walk back a term decision, implying that FDA had made a regulatory determination, which they had not." JVH Decl., Ex. 49 at 98:18-100:3. According to the FDA "Team Lead":

> Informal communications with FDA staff do not represent the formal position of FDA and do not bind or otherwise obligate or commit the agency to the views expressed. This is why there is nothing for Rebotix to appeal at this time.

JVH Decl., Ex. 48.

IV. STANDARD OF REVIEW

Summary Judgment is proper when the record shows "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). A factual issue is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material if it is necessary to prove or defend against a claim, as determined by the applicable substantive law. *Id.* at 255. Although "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor" (*id.* at 255), a court may disregard the non-movant's version of the facts where it is "blatantly contradicted by the record, so that no reasonable jury could believe it." *Scott v. Harris*, 550 U.S. 372, 380 (2007).

V. ARGUMENT - INTUITIVE'S FDA-RELATED DEFENSES AND COUNTERCLAIMS SHOULD BE DISMISSED

Intuitive's unfair competition and false advertising claim under the Lanham Act (Count 1) and its derivative state law claims (Counts 2-4) allege in part that "SIS has made numerous false and misleading statements, including . . . that the 'repair' and/or resulting instruments do not require clearance by the FDA[.]" Dkt. 75 at at ¶ 85. However, any SIS statements that it did not require clearance by the FDA cannot be false or misleading where FDA has not enforced regulations against SIS or issued standards on the underlying issue of what activities constitute remanufacturing, and thus require 510(k) clearance.

Although the default rule from *POM Wonderful*[10] is that Lanham Act claims can coexist with FDA's enforcement and regulatory authority, Intuitive's Lanham Act claims[11] not only require the Court to make rulings that might be duplicative or conflicting with potential FDA rulings, but would also require the Court to step into the role of the role of a regulator that has

[10] *POM Wonderful LLC v. Coca-Cola Co*. 573 U.S. 102, 115 (2014).

[11] In contrast to Intuitive's claims, SIS's Lanham Act claims are based on Intuitive falsely asserting that SIS can be in violation of FDA rules that have never been enforced or finalized.

spent years (indeed decades) considering the exact issue without ever issuing "final guidance."[12]

This is not a situation where statutory and regulatory provisions are "clear in the relevant respects, and that clear statutory text is reinforced by the FDA's . . . guidance." *Azurity Pharm. v. Edge Pharma*, *LLC*, 45 F.4th 479, 501 (1st Cir. 2022). Rather, deciding in the first instance the standard for distinguishing "repair" from "remanufacturing" would "require a court to make a determination that 'l[ies] at the heart of the task assigned the agency by Congress[.]'" *Id.* (quoting *Pejepscot Indus. Park, Inc. v. Me. Cen. R.R. Co.,* 215 F.3d 195, 205 (1st Cir. 2000)). Simply put, there is "a lack of guidance from the FDA about an unclear statutory question, the resolution of which implicate[s] the FDA's expertise[.]" *Azurity Pharm*., 45 F.4th at 501 (discussing *Amarin Pharma, Inc. v. Int'l Trade Comm'n*, 923 F.3d 959 (Fed. Cir. 2019)).

Although the line for allowable *Lanham Act* claims that can be resolved post-*POM* may not be entirely clear, Courts have repeatedly determined that this line is crossed where a ruling by the Court would "directly implicate the FDA's rulemaking authority" or where "the law is unclear and the FDA's particular expertise or rulemaking authority is required[.]" *World Nutrition Inc. v. Advanced Enzymes U.S.*, No. CV-19-00265-PHX-GMS, 2021 WL 632684, *3 (D. Ariz. Feb. 18, 2021) (quoting *Allergan USA Inc. v. Imprimis Pharms., Inc.*, No. SA CV 17-1551-DOC, 2017 WL 10526121, at *7 (C.D. Cal. Nov. 14, 2017) and *JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 1000 n.5, 1004 (C.D. Cal. 2014)).

[12] The fact that Intuitive has found an expert willing to testify that "FDA's definition of remanufacturing has been clear since the promulgation of 21 CFR 820 in 1996" (JVH Decl. Ex. 50 at ¶ 69) and base an entire opinion on that assumption is irrelevant where FDA itself clearly disagrees. *See* §§ III(D)-(E), *supra* (discussing years of workshops, white papers, comments, and draft guidance to "Clarify the Difference Between Servicing and Remanufacturing"); FDA Public Meeting, October 27, 2016 (JVH Decl. Ex. 43) at 17-18 (FDA describing 1996 rulemaking to "cover third-party service organizations" and explaining that "this is where the refurbisher, reconditioner, servicers, all that verbiage comes from. . . . At that time no one could agree what the right term was. And I think we are still at that point where nobody really knows what the best term to use for this particular situation is."); *Scott*, 550 U.S. at 380 (explaining that a court may disregard the non-movant's version of the facts on summary judgment where it is "blatantly contradicted by the record, so that no reasonable jury could believe it"). In sum, if the definition of remanufacturing has been clear since the 1996, why would the OEM trade organizations have pushed legislation just last year entitled the "Clarifying Remanufacturing to Protect Patient Safety Act of 2022''?

As discussed in detail in Section III(D), despite years of public and private pressure from OEMs, FDA still has not made an original determination as to the standards that ISOs may use to determine whether their activities constitute remanufacturing. *See Belcher Pharm., LLC v. Hospira, Inc.*, 1 F.4th 1374, 1380 (11th Cir. 2021) (approving of "cases recognizing that Lanham Act claims may be barred if their resolution requires an original determination that is committed to the FDA"); *cf. Rebotix Repair LLC v. Intuitive Surgical, Inc.*,[13] 8:20-cv-2274-VMC-TGW, 2022 WL 3272538 at *6-7 (M.D. Fla. Aug. 10, 2022) ("For the reasons stated above, the Court will not at this juncture issue a determination with respect to whether or not Rebotix's services and/or products require Section 510(k) clearance.").

To the extent that the Court can rule on Intuitive's FDA-related claims, SIS's statements are not false or misleading. For example, SIS's statement that "[t]he da Vinci® EndoWrist® is a 'multi-use' medical device [and] Multi-use devices, such as endoscopic instruments, have always been eligible for repair" was confirmed by FDA: "So the industry has not really had any involvement with FDA except our interactions with some of the trade associations since 1998." FDA Public Meeting, October 27, 2016 (JVH Decl., Ex. 43) at 20-21. SIS's statement that "[t]he FDA does not regulate, nor certify, repairs [and instead] regulates third party reprocessing companies and single-use devices only" is consistent with FDA's actual regulatory conduct, as well as its statutory authority.[14] *Compare* § III(B), *supra*, (discussing

[13] The District Court in *Rebotix* declined to grant summary judgment on Intuitive's counterclaims because FDA might change its mind before trial. *Rebotix Repair*, 2022 WL 3272538 at *6 ("If, however, the FDA has not issued an official, final determination on this issue on the eve of trial, the Court invites Rebotix to renew its motion for summary judgment as to these counterclaims."). That decision, however, was based primarily upon Rebotix's correspondence with FDA declining to issue an appealable decision. Although this correspondence further supports SIS's motion, the key issue raised by the present motion is FDA's failure to issue final guidance at the time of SIS's purportedly false statements.

[14] To the extent that FDA may someday officially promulgate regulations and guidance that require 510(k) clearance for repair of hospital-owned multi-use devices such as that performed by SIS (including EndoWrists), it may run into substantial issues of whether it has statutory authority do so. *Compare West Virginia v. Environmental Protection Agency*, 142 S.Ct. 2587, 2614 (2022) ("[W]e cannot ignore that the regulatory writ EPA newly uncovered conveniently enabled it to enact a program that, long after the dangers posed by greenhouse gas emissions "had become well known, Congress considered and rejected" multiple times.") *with* § III(C), *supra* (discussing OEMs' repeated failed attempts to pass statutes requiring 510(k) clearance for "servicing" and "remanufacturing") *and* § III(D), *supra* (FDA noting that it did not issue definitive regulations because "there was a lot of contentious discussions

statute authorizing FDA regulation of reprocessing of single-use devices) *with* § III(C), *supra* (OEMs repeatedly failing to pass legislation authorizing FDA to regulate "servicing" and "remanufacturing," and Congress explictly asking FDA to provide "a description of the statutory and regulatory authority" over servicing and remanufacturing and "whether additional authority is recommended"). SIS's statements are also consistent with FDA's actions on the specific issue of whether "[s]ome components/parts/materials have a defined intended use life which limits the life expectancy of the device . . . [and] [a]ctivities are performed to extend the device's intended use life." As discussed at § III(E), *supra*, FDA has not only declined to decide on final standards as to what constitutes remanufacturing, it also dropped all discussion of the specific issue of extension of intended use life from its draft guidance and capitulated to Rebotix when it requested a right to appeal to proper authorities within FDA.

Finally, for the same reasons that Intuitive cannot prevail on its FDA-related *Lanham Act* claims, SIS cannot possibly have engaged in unclean hands on these FDA issues. "To prevail on a defense for unclean hands in response to a Lanham Act claim, [a party] must show that [the other party's] conduct . . . "was 'inequitable' or 'unconscionable[.]" *First Ascent Ventures Inc. v. DLC Dermacare LLC*, 312 Fed.Appx. 60, 61 (9th Cir. 2009); *see also Wheeler v. Am. Family Home Ins. Co.*, 20-cv-01502-JSW, 2022 WL 4624863 at *7 (N.D. Cal. Sep. 30, 2022) ("The doctrine of unclean hands requires unconscionable, bad faith, or inequitable conduct by the plaintiff in connection with the matter in controversy.").

"Though the party against whom unclean hands is enforced need not have acted unlawfully, the court may only apply the doctrine where the party committed a 'willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct.'" *LL B Sheet 1, LLC v. Loskutoff,* 362 F. Supp. 3d 804, 821 (N.D. Cal. 2019) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 815 (1945)). In the present case, SIS cannot be said to have acted "willfully" when FDA doesn't even

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about it . . . [a]nd it got to the point where this particular subject could have derailed the proposed rule from becoming final").

know what standards it will enforce on remanufacturing and has twice punted on the specific question of life extension of limited-use devices.

VI. CONCLUSION

For the foregoing reasons, SIS respectfully requests that the Court grant partial summary judgment on Intuitive's counterclaims 1-4 and its unclean hands affirmative defense as they relate to FDA.

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